# Tobacco Regulatory Science

## P30 Webinar
## National Institutes of Health
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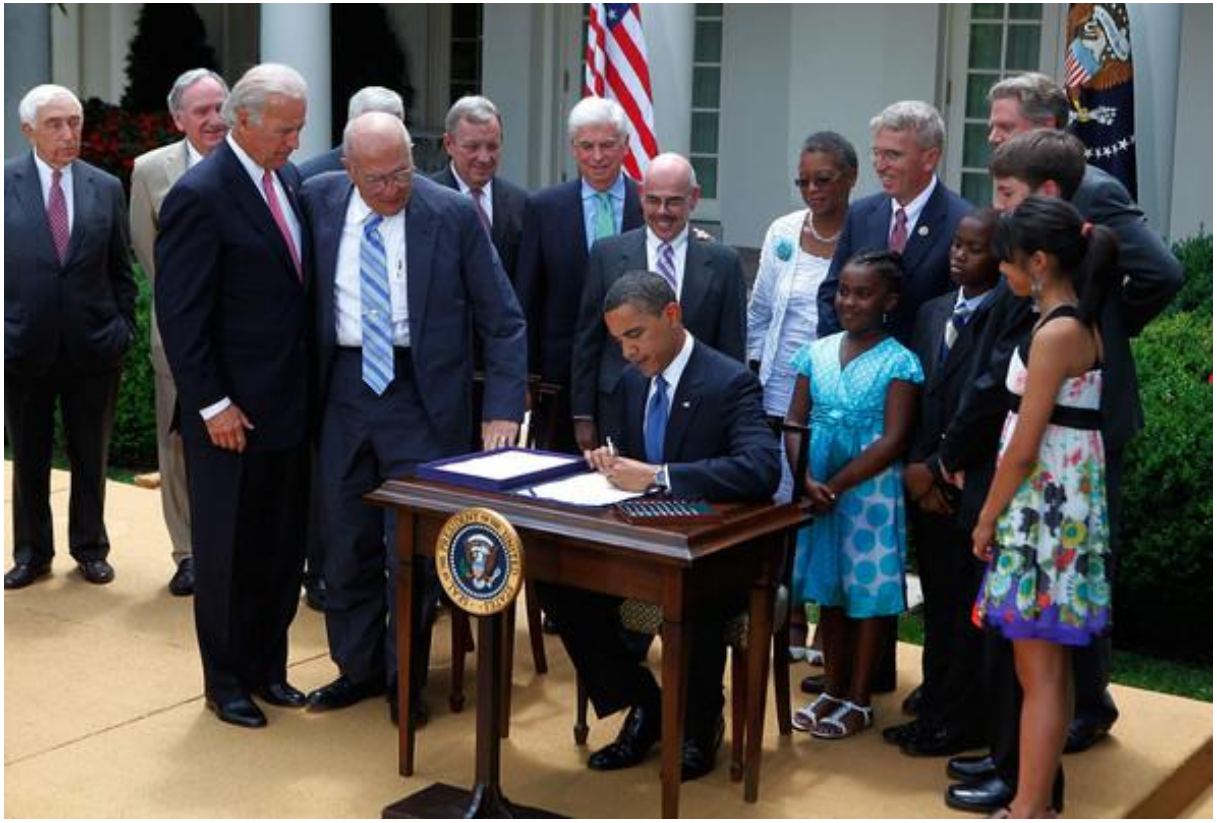
# Family Smoking Prevention and Tobacco Control Act
# June 22, 2009



# FDA Authority Under the Tobacco Control Act

- Gives FDA direct authority over cigarettes, roll-your-own and smokeless tobacco products
- "Tobacco product" is defined any product made or derived from tobacco that is intended for human consumption, including any component part, or accessory of a tobacco product
- FDA announced that it will propose a rule deeming products that meets the definition of a "tobacco product" to be subject to FDA's jurisdiction
- CTP funded solely via "user fees" from tobacco company assessments - $505 million for FY13
  - caps at $712 million in FY19

# FDA/CTP Public Health Goals

- Prevent Americans—especially youth—from starting to use tobacco
- Encourage current users to quit
- Decrease the harms of tobacco product use

# CTP Uses a Public Health/Population Health Regulatory Standard

- Tobacco products cannot be regulated using FDA's traditional "safe and effective" standard
- The Tobacco Control Act mandates its regulation using a population health standard taking into account both users and non-users of tobacco products

# Specific Authorities Include:

- Premarket applications for new and modified risk tobacco products
- Testing and reporting levels of harmful and potentially harmful constituents by brand and sub-brand
- Tobacco product standards
- Health warnings on cigarettes and smokeless tobacco products & ads
- Advertising and promotion restrictions
- Industry registration and listing of ingredients
- FDA has authority to conduct research to support tobacco product regulation

# Tobacco Control Act -- Limitations

In general, CTP's regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by CDER, FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine levels to zero

# FDA-CTP Research Areas of Interest

- Nicotine dependence threshold among youth and adults and impact of nicotine reduction on tobacco product use behavior
- Initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence and toxicity of:
  - Cigars (small, large, cigarillos), smokeless tobacco, e-cigarettes, hookah, pipes, dissolvables
- Impact of tobacco product characteristics (e.g., ingredients, constituents, components, additives such as flavors, and labeling and marketing) on initiation

# FDA-CTP Research Areas of Interest

- Toxicity thresholds for each of the 20 harmful and potentially harmful constituents
- Statistical modeling of the public health impact of FDA/CTP regulation of potential modified risk tobacco products
- Consumer perceptions of tobacco products including the impact of labeling and marketing
- Effective communication strategies regarding harmful and potentially harmful constituents and risks of tobacco products

# FDA-CTP Research Priorities Differ from NIH Priorities

- FDA-CTP funds cannot be used to support research on:
  - Diagnosis of disease
  - Treatment of disease or tobacco use
  - Mechanisms of disease
  - Clinical practice
- Tobacco regulatory science
  - Research to inform FDA's regulatory authority with respect to manufacture, marketing, and distribution of tobacco products

# FDA's Framework for Tobacco Product Regulation

1. Understand the regulated products
2. Control product changes that could impact public health
3. Prohibit false/misleading product claims that state/imply reduced risk
4. Restrict marketing and distribution, particularly to youth
5. Decrease the harms of the product
6. Ensure industry compliance
7. Educate the public related to FDA's regulatory actions
8. Expand the science base for regulatory action & evaluation

# Changes to or New Tobacco Products now require FDA Review

| Tobacco Product Introduced: | Defined: | Submission to FDA: | Continue to Market or Start Marketing? |
|---|---|---|---|
| As of Feb. 15, 2007 (no changes) | "Grandfathered" | Optional | Yes |
| From Feb 16, 2007 and Mar. 21, 2011 (or changed) | "Provisional New Tobacco Product" | Substantial Equivalence Report (submit by March 22, 2011) | Yes (Unless found NSE) |
| On or after Mar. 22, 2011 (or changed) | "Regular New Tobacco Product" | New Product: Pre-Market Application ("PMTA") | No (Need order from FDA) |
| | | Substantial Equivalence "SE" Report | |
| | | SE Exemption Report | |
| Any time | = Proposed Modified Risk Tobacco Product | Modified Risk Tobacco Product Application ("MRTPA") +/- PMTA | No (Need order from FDA) |

# Pathways to Market

Substantial Equivalence - Section 905:

Does the new product have the same characteristics as a predicate or do the changes raise new questions of public health?

- Design Features
- Ingredients
- Materials
- Heating Source
- Composition
- Other Features: Harmful/Potentially Harmful Constituents
- Consumer perception
- Abuse liability
- Toxicology

# Pathways to Market

Premarket Tobacco Products - Section 910:

Would permitting such a product to be marketed be appropriate for the protection of public health?

- Full reports of investigations of health risks
- All components, ingredients, additives, properties, and principles of operation
- Methods of manufacturing and processing
- Compliance with tobacco product standards
- Product samples and components
- Proposed labeling
- Product chemistry
- Nonclinical studies
- Studies in adult human subjects

# Modified Risk Tobacco Products

Section 911: Would marketing of such a product significantly reduce harm and the risk of tobacco-related disease and benefit the health of the population as a whole?

- Description of the product and any proposed labeling and advertising
- Conditions for using the product
- Formulation of the product
- Sample product labels and labeling
- All documents related to research findings
- Data and information on how consumers actually use the product

# Tobacco Product Standards

Section 907: Standards appropriate for the protection of public health can apply to any regulated tobacco product on the market under FDA authority and can include provisions for:

- Nicotine yields
- Reduction or elimination of constituents, including smoke constituents
- Construction, components, ingredients, additives, constituents, and properties of the tobacco product
- Provisions for testing or measuring product characteristics
- Restricting sale and distribution
- Form and content of labeling for the proper use of the product